

Morrison Medical Products
Cinch Strap with Buckle

NOV - 8 1996

Safety and Effectiveness Summary**1. Submitter's name, Address and Contact Person**Submitter

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Contact Person

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2. Name of Device:

Cinch Strap with Buckle

3. Name of Predicate Device(s)

Cinch Strap with Buckle

4. Description of Device

The Morrison Medical Products Cinch Strap with Buckle is intended to limit a patient's movement to the extent necessary for treatment, examination, or protection of the patient or others. The device can be used in the supine or sitting position. The device is also intended to be used as an assist in securing equipment.

The Cinch Strap with Buckle is constructed of a nylon hook and loop material. Heat Sealed to one end is a nylon hook material that is used to secure the patient or equipment in the Cinch Strap with Buckle. The Cinch Strap with Buckle is available in the following sizes:

Series 1142 - 1" x 42"
Series 1150 - 1½" x 18"
Series 1160 - 1½" x 30"

5. Statement of Intended Use

The Morrison Medical Products Cinch Strap with Buckle is intended to limit the patient's movement to the extent necessary for treatment, examination, or protection of the patient

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or others. The device can be used in the supine or sitting position. The device is also intended to be used as an assist in securing equipment.

6. Statement of Technological Characteristics of the Device

The subject devices are identical in intended use, design, materials, manufacturing process, physical and mechanical specifications and issues of safety and effectiveness to the devices prior to the submission of this notification. The only difference is that the product labeling has been revised to comply with the Agency's labeling requirements set forth in the draft "Guidance on the Content of Premarket Notification [510(k)] Submissions for Protective Restraints" dated December 1995.

7. Biocompatibility

The subject devices are identical in component materials to the predicate devices. A biocompatibility review of these materials indicated little potential to evoke an adverse reaction. In addition, Morrison Medical Products is not aware of any reports or complaints of skin irritation associated with these materials.

8. Conclusion

Based upon the information presented above it is concluded that the proposed Morrison Medical Products Cinch Strap with Buckle is safe and effective for its intended use and is substantially equivalent to the predicate device.